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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,915	06/29/2006	Raghupathi Kandarapu	GEN 3.3-008	2317

45776 7590 11/19/2009

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EXAMINER	
LOVE, TREVOR M	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
11/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patpros@drreddys.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,915	KANDARAPU ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made to Applicant's response filed 08/11/2009.

Claims 1 and 3-20 are pending and currently under consideration.

Claim 2 is cancelled.

Claim 1 is currently amended. It is noted that while Applicant states that the amendment to claim 1 incorporates the limitation of now cancelled claim 2, the examiner disagrees. Now cancelled claim 2 formerly recited a limitation to the pharmaceutically active ingredient, whereas newly amended claim 1 now recites a limitation to the subcoating.

Withdrawn Rejections

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Close et al is withdrawn in view of applicant's cancellation of said claim.

Claim Objections

(Necessitated by Amendment)

Claims 9-11 are objected to for depending from cancelled claim 2. For the sake of compact prosecution the claims are being interpreted as depending from independent claim 1. Appropriate correction or cancellation of said claims is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-9, and 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Close et al (European Patent number 0094116 (A2), published Nov. 16, 1983).

Close teaches therapeutic, enteric coated granules which comprise a non-steroidal, therapeutic active core, wherein said core is coated by a first coating, which is subsequently coated with an enteric coating. Said first coating comprises a dispersing aid (see claim 1). Said dispersing aid is taught as being either an alkali metal phosphate or glycine (see claim 8), said glycine is water soluble. Said dispersing aid is present in an amount of approximately 0.5 to 7.5 (see claim 1), with a preferred embodiment being taught in example II being approximately 3.5% of the entire weight of the granules. The active core is taught as being selected from a plurality of active agents, all of which have some sensitivity to acid. Said active can also comprise an antihistamine (see page 4, line 27).

Response to Arguments

Applicant argues in the remarks filed 08/11/2009 that "[a]pplicants cannot find any indication in the document that indicates acid sensitivity of the disclosed active agents, or that acid sensitivity was even considered to be relevant". Furthermore,

applicant states that the enteric coatings generally are applied not to protect the aspirin, but to protect the stomach against contact with the irritating drug. Applicant's arguments have been fully considered and are not found persuasive. Specifically, the composition of Close is the same as the instant invention. For instance, Close teaches that antihistamines can be the present (see page 4, line 27), which is one of the instantly claimed acid sensitive pharmaceutically active ingredients. It is noted that MPEP 2112.01 states: "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." It is further noted that the art is not required to teach the same reasoning for adding components as applicant, MPEP 2144 (IV) states "the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by Applicant. See, e.g., In re Kahn, 411 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)." Applicant further argues that the composition of Close would include additional components which could contact the enteric coating layer. Applicant argues that this would not be desired for the products of the present invention. Applicant's arguments

are not found persuasive since Applicant utilizes "comprising" language which allows for additional components to be present. MPEP 2111.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-11 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Close et al (European Patent number 0094116 (A2), published Nov. 16, 1983) in view of Henriksen (U.S. Patent number 6,391,342, Patent published May 21, 2002).

The teachings of Close are set forth above under the discussion of 35 U.S.C. 102(b).

Close fails to directly teach that said active core comprises an antidepressant, and particularly a benzimidazole proton pump inhibitor.

Henriksen teaches an oral dosage form comprising a benzimidazole proton pump inhibitor as an innermost layer with an enteric coating as the outermost layer. Henriksen teaches that in order to protect the benzimidazole proton pump inhibitor from degradation by the ingredients of the enteric coating that an intermediate coating layer is required (see claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the benzimidazole proton pump inhibitor as the active core in the invention of Close. One would have been motivated to do so since utilizing a benzimidazole proton pump inhibitor as the active would allow the composition to be used to treat a wider variety of conditions, and benzimidazole proton pump inhibitors are taught in Henriksen as requiring an intermediate layer to protect the benzimidazole proton pump inhibitor from the ingredients of the enteric coating. There would be a reasonable expectation of success in the use of the benzimidazole proton pump inhibitor of Henriksen as the active of Close since Close teaches that additional

components, including actives, can be incorporated into the core (see Close, page 4, lines 26-29).

Response to Arguments

Applicant argues in the remarks filed 08/11/2009 that Henriksen does not teach the presence of alkaline substances, and therefore, one "substituting teachings of an alkaline substance from any source into this document would be in opposition to its plain teachings." Applicant's argument is not found persuasive since the premise of the argument is that teachings are being substituted into the teaching of Henriksen. It is noted that Close is the primary reference, and Henriksen is relied upon as a secondary reference to modify Close. In said combination, it would have been obvious to one of ordinary skill to utilize the benzimidazole proton pump inhibitor of Henriksen in the invention of Close to allow for the composition of Close to be utilized to treat a broader range of disorders, and Henriksen teaches that the active of Henriksen requires an intermediate layer, which is the same as the coating system of Close. Therefore, applicant's arguments are not found persuasive.

Conclusion

No claims allowed. All claims rejected. No claims objected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643